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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,386	04/03/2002	Sharron Gaynor Penn	PB-01106	4235
22840	7590	06/15/2004	EXAMINER	
AMERSHAM BIOSCIENCES PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855				MARSCHEL, ARDIN H
ART UNIT		PAPER NUMBER		
		1631		

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/029,386	PENN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 February 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-109 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ .   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

It is noted that applicants have submitted additional inventions in amended claims. Therefore, yet another reconsideration of the instant application, as deemed appropriate, has revealed that numerous patentably distinct inventions are included in various claims which were not previously made subject to a restriction/election requirement. This Office action therefore vacates the previous restriction/election requirement, mailed 1/29/04, and replaces it with the following new set of restriction/election requirements. The election, filed 2/25/04, by applicants is acknowledged. Due to the below set forth newly applied restriction/election requirements, applicants are hereby required to re-elect an appropriate invention for examination. It is noted that applicants have not set forth any arguments as to why all of claims 54-109 are contained within the subject matter of the previously set forth Group V.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28 and 44, drawn to a nucleic acid probe for measuring human gene expression selected from SEQ ID Nos: 13,701-27,400 and Tables 4-11 and vectors, classified in class 536, subclass 23.1, and class 435, subclass 320.1. If this Group is elected then the below summarized sequence election is also required.
- II. Claims 29-35, drawn to a set of single exon nucleic acid probes for measuring human gene expression, classified in class 702, subclass 19.

If this Group is elected then the below summarized sequence election is also required.

- III. Claims 36-40, drawn to a microarray for measuring human gene expression comprising a plurality of single exon probes, classified in class 422, subclass 68.1. If this Group is elected then the below summarized sequence election is also required.
- IV. Claims 41-43, drawn to a method of measuring human gene expression using a microarray, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.
- V. Claims 45-46, drawn to an ORF-encoded peptide, classified in class 530, subclass 300 or 350, for example. If this Group is elected then the below summarized sequence election is also required.
- VI. Claim 47, drawn to an antibody, classified in class 424, subclass 130.1. If this Group is elected then the below summarized sequence election is also required.
- VII. Claims 48, 49, and 54-88; drawn to a method of selling and/or licensing, classified in class 705, subclass 26. If this Group is elected then the below summarized sequence election is also required.
- VIII. Claim 50, drawn to a method of providing human gene expression data by subscription by making a database available, classified in class 707, subclass 3. If this Group is elected then the below summarized sequence election is also required.

- IX. Claim 51 and 53, drawn to a computer readable storage medium, classified in class 707, subclass 100. If this Group is elected then the below summarized sequence election is also required.
- X. Claim 52, drawn to a computer system, classified in class 700, subclass 1. If this Group is elected then the below summarized sequence election is also required.
- XI. Claims 89-109, drawn to a method of manufacturing a microarray, classified in class 536, subclass 25.3. If this Group is elected then the below summarized sequence election is also required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence, or, a specific set thereof. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence, or, a specific set thereof, such as in claims directed to a plurality of sequences. Specific to Group XI only another sequence election may be substituted therewith for the above which is directed to generic, not instantly specified, probe sequences because claim 89, for example, is not limited to requiring any specific sequence as set forth in the instant application (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement. It is acknowledged that the instant

claims are inclusive of embodiments of invention directed to one, a plurality, a set, or even large sets of sequences (See, for example, instant claims 29 and 31.). In recognition of these embodiments, applicants may elect, one of the alternatives of, one specific sequence or a specific set of sequences defined by SEQ ID NOs:, for example.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence, or set of sequences. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

### **RESTRICTION GROUP DISTINCTIONS**

The inventions are distinct, each from the other because:

The independence or distinctness between biopolymer sequences has been set forth above.

The invention Groups are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, III, IV, VII, and XI); Groups (V); Group (VI), and Groups (VIII, IX, and X) are independent inventions because they are directed to different chemical or informational types of inventions regarding the critical limitations

therein. For Group V the critical feature is a peptide; for Groups I, II, III, IV, VII, and XI the critical feature is nucleic acids; for Group VI the critical feature is an antibody, and for Groups VIII, IX, and X the critical feature is computer information and/or business processing. It is acknowledged that various processing steps may cause a peptide of Group V to be directed as to its synthesis by a polynucleotide of Groups I, II, III, IV, VII, or XI, etc., however, the completely separate chemical or computer informational or business processing types of the inventions of the nucleic acid, polypeptide, antibody, and computer/business Groups supports the undue search burden if any two Groups were examined together. Additionally, polynucleotides, peptides, antibodies, and computer/business methods have been most commonly, albeit not always, separately characterized and published in the literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, etc. Thus, the above listed three Groupings are independent and/or distinct invention types for restriction purposes.

The inventions of Group XI and Groups I, II, III, IV, and VII are related as process of making and products made and use thereof. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products and corresponding uses thereof may arise from general sequencing data, directed to desired sequences for a wide variety of gene expression studies, from

sequencing of the human genome as is now well known in the art which is distinct from from some type of customer request as set forth in Group XI.

The inventions of Groups I, II, III, IV, and VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the composition/product Groups I, II, and III are each directed to distinct compositions/products due to the search being distinct as directed by usages thereof. Group I is directed to a single exon and as such is generally analyzed, found, and used for specific gene or exon diagnosis studies, for example for mutation detection. Group II is directed to multiplex exon sets that are directed to expression profiling or, alternatively, for multiplex therapy studies and/or treatment directed to exon and/or gene sets which brings up issues of coordination of effects, side effects, etc. Group III is directed to expression profiling on a microarray which may be alternatively be utilized for expression profiling, sequencing, disease diagnosis, and drug discovery studies some of which are distinct from the above discussed usages. The methods of Groups IV and VII are themselves distinct usages of the probes being directed to microarray expression profiling (Group IV) or, the distinct usage of selling and/or licensing of probe information compared to the above listed distinct usages.

The inventions of Groups VIII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the computer storage medium of Group IX is directed to computer program and data storage whereas, in contrast, the inventions of Groups VIII and X are directed to a programmed computer (Group X) that may or may not be utilized in any procedure as compared to the method of Group VIII directed to actually providing human gene expression data.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 11, 2004

Ardin W. Marschel 6/11/04  
Michael Woodward, Ph.D.  
Tina Plunkett